NOVABONE
DRIVING INNOVATION IN OSTEOBIOLOGICS

MAR 3 0 2010

K100671

Special 510(k): Device Modification Summary 03/04/10
NovaBone Dental Putty – Bioactive Synthetic Bone Graft

1. Submitter Information:

Name:	NovaBone Products, LLC
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Telephone:	(386) 462-7660
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Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone Dental Putty – Bioactive Synthetic Bone Graft
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 872.3930
Regulation Name:	Bone Grafting Material, Synthetic

3. Legally Marketed Predicate Device:

Predicate #1:	NovaBone Dental Putty – Bioactive Synthetic Graft [K091484]
Predicate #2:	NovaBone Dental Putty – Bioactive Synthetic Graft [K063549]

4. Device Description

NovaBone Dental Putty is an osteoconductive, bioactive, bone void filler device. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects and is supplied sterile. It is composed of a calcium-phosphorus-sodium-silicate particulate mixed with a synthetic binder that acts as a temporary binding agent for the particulate. The particulate and binder are provided premixed as a pliable cohesive material. The mixed device is supplied sterile, packaged either in a PET-G tray or in a disposable plastic syringe or cartridge. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles are slowly absorbed and replaced by new bone tissue during the healing process. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects. It is supplied sterile.

5. Intended Use

The intended use of NovaBone Dental Putty is to provide a safe, biocompatible synthetic bone graft material for use in oral, dental intraosseous, and craniofacial defects. It is used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (Demineralized Freeze Dried Bone) or may be mixed with either (typically 1:1 ratio v/v) as a bone graft extender. Typical uses include:

- Periodontal/Infrabony defects
- Ridge Augmentation (sinusotomy, osteotomy, cystectomy)
- Extraction sites (ridge maintenance/augmentation, implant preparation/ placement)
- Sinus lifts
- Cystic cavities
- Cranio-facial augmentation

For larger defects, a mixture of NovaBone Dental Putty with an equal volume of allograft or autograft bone and bone marrow may improve new bone formation.

6. Technological Characteristics

The technological characteristics of the NovaBone Dental Putty device are similar to those of the predicates. The device and the predicates are designed as osteoconductive space-filling devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. The device indications are unchanged from those of the predicate devices. The device is intended to be used alone, or in combination with autogenous or allograft bone.

The NovaBone Dental Putty device of this submission is identical in composition to the NovaBone Dental Putty predicate devices; no changes to the device formulation or function have been made. The primary component of NovaBone Dental Putty is a calcium phospho-silicate particulate, a synthetic material that is both biocompatible and osteoconductive. The NovaBone Dental Putty includes a synthetic binder as an inert carrier for ease of handling and delivery, forming a premixed cohesive material. The binder is biocompatible and is absorbed after implantation, opening space between the bioactive glass particles for cell infiltration and bone formation. The bioactive glass particulate remains for a longer post-implantation period, acting as a scaffold for bone ingrowth. This particulate is absorbed and replaced by new bone tissue.

The filled-cartridge package format as described in this submission is a product line extension, increasing the device package format availability. The new packaging aids in device placement, permitting a different mode of application distinct from that of the previously cleared predicates packaged in tray-in-pouch [K063549] and syringe-in-pouch [K091484] formats. The cartridge packaging system itself is similar to the Class I devices as defined in premarket applications K882551 (cartridge) and K832662/K915147 (cartridge syringe applicator).

7. Conclusion

The NovaBone Dental Putty device modification subject to this submission is to include a filled-cartridge package format to augment the current package configurations. This device modification does not result in a change in

technological characteristics of the device. NovaBone Putty continues to be safe and effective as a non-structural osteoconductive bone void filler for osseous defects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David M. Gaisser
Vice President
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13631 Progress Boulevard, Suite 600
Alachua, Florida 32615

MAR 3 0 2010

Re: K100671
Trade/Device Name: NovaBone Dental Putty-Bioactive Synthetic Bone Graft
Regulation Number: 21CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: March 4, 2010
Received: March 9, 2010

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100671

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: NovaBone Dental Putty – Bioactive Synthetic Bone Graft

Indications For Use:

The intended use of NovaBone Dental Putty is to provide a safe, biocompatible synthetic bone graft material for use in oral, dental intraosseous, and craniofacial defects. It is used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (Demineralized Freeze Dried Bone) or may be mixed with either (typically 1:1 ratio v/v) as a bone graft extender. Typical uses include:

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Prescription Use XX OR (Per 21 CFR 801.109) Over-The-Counter Use____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. K.P. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100671